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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER
LANDSMAN, ROBERT S

ART UNIT	PAPER NUMBER
1647	

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15

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/982,543	DIJKE ET AL.	
	Examiner	Art Unit	
	Robert Landsman	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 March 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-27* is/are pending in the application.

4a) Of the above claim(s) *6,7 and 11-27* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *11* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *Sequence Comparisons A-L*

AC 5/8/03

DETAILED ACTION

1. Formal Matters

A. Claims 1-27 are pending and were subject to restriction in Paper No. 12, dated 12/18/02. In Paper No. 14, filed 3/17/03, Applicants elected Group I, claims 1-5 and 8-10, with traverse. Applicants argue that a search of Group I would encompass a search of Group II as well as the product by process claims of Group III. Applicants also argue that, if Group III is searched, then Groups VIII and IX should be combined. Applicants also argue that it would not be an undue burden to search SEQ ID NO:3 and 5 along with SEQ ID NO:7 and that a search for ALK-6 would encompass a search for ALK-2 and ALK-3. These arguments have been considered, but are not deemed persuasive.

First, as stated in the restriction, the methods of Groups I and II are independent and distinct. Group I is drawn toward a method of identifying OP-1 receptor binding analogs. The methods in these claims do not require a search of any OP-1 receptor binding analogs, or their methods of production. Methods of identifying analogs only require the receptor (i.e. protein) of interest and numerous test compounds. Methods of producing analogs may require, for example, chemical synthesis techniques, or synthetic protein production. Furthermore, screening methods do not require that the analogs be known. Therefore, no separate search of any analogs, or their methods of synthesis, would be required for the methods of Group I, as would be the case for Group II. Similarly, Group III recites compounds and a search of these compounds would not overlap a search for methods of screening. In addition, the compounds in Group III require synthesis, since the claims recite "the compounds produced by the methods of claims 1-8..." Group I only requires screening compounds, not their production. Since Group III is not being recombined with Group I, Groups VIII and IX will also not be combined. Finally, the protein of ALK-2, ALK-3 and ALK-6 are all identified by separate SEQ ID NOs. Therefore, a search of SEQ ID NO:7 would not necessarily overlap a search for the other SEQ ID NOs. In addition, Applicants were required to elect one primer (SEQ ID NO:12-15) to be searched. Regardless, the Examiner has decided to search SEQ ID NO:4, 6 and 8 as well as all primers, SEQ ID NO:12-15. As written, the claims are not an undue burden. However, if further limitations are included in the amended claims, or if the number or complexity of the claims becomes too great, the Examiner will consider another restriction of the claims. As of now, Group I, claims 1-5 and 8-10, in full, are the subject of this Office Action. This restriction is deemed proper and is, therefore, made FINAL.

2. Information Disclosure Statement

A. Reference BH on the Form PTO-1449, filed 7/22/02, has been lined through since no journal name, publication date, or other information required to identify this reference has been provided.

3. Oath/Declaration

A. The Declaration is objected to since it is not clear why reference is made to US Application 08/236,428, nor is it clear why the box identifying this application as a "national stage of PCT" is not checked for the Declaration signed by Miyazono.

4. Specification

A. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. The claims are drawn to methods of identifying OP-1 receptor-binding analogs.

B. The specification is objected to since reference to PCT/US95/05467 was not recited in the first line of the specification.

C. The specification is objected to since there is no specific SEQ ID NO recited on page 11, line 29.

5. Claim Objections

A. The syntax of claims 1, 2 and 8 could be improved by removing one of the commas after "(ALK-6)."

B. Claim 5 is objected to since the claim should recite "any one of claims 1, 2, 3, or 4."

6. Claim Rejections - 35 USC § 112, first paragraph – scope of enablement

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

A. Claims 1-5 and 8-10 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for method of identifying binding analogs which interact with the claimed fragments of SEQ ID NO:4, 6 and 8, does not reasonably provide enablement for methods of identifying binding analogs of proteins which are at least 40% identical to residues 23-132 of SEQ ID NO:8, or any polypeptide chain which is amplified by the primers of SEQ ID NO:12-15, or which hybridizes to residues 256-552 of SEQ ID NO:8. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

In In re Wands, 8USPQ2d, 1400 (CAFC 1988) page 1404, the factors to be considered in determining whether a disclosure would require undue experimentation include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

First, the breadth of the claims is excessive with regard to claiming methods of identifying binding analogs of proteins which are **at least 40% identical** to residues 23-132 of SEQ ID NO:8, or any polypeptide chain which is amplified by the **primers** of SEQ ID NO:12-15, or which **hybridizes** to residues 256-552 of SEQ ID NO:8. Nucleic acid molecules which "hybridize" to SEQ ID NO:7 (which encodes SEQ ID NO:8), or which hybridizes to SEQ ID NO:12-15, would have one or more nucleic acid substitutions, deletions, insertions and/or additions to the polynucleotide of SEQ ID NO:7. Similarly, proteins which are "at least 40% identical" to the protein of SEQ ID NO:8 would encode for a protein with one or more amino acid substitutions, deletions, insertions and/or additions to the protein of SEQ ID NO:8.

Applicants have only identified ALK proteins of SEQ ID NO:4, 6 and 8 and that OP-1 binds these receptors (Table II of the specification – page 43). Applicants provide no guidance or working examples of proteins other that those of ALK-2, 3 and 6 (SEQ ID NO:4, 6 and 8) which are able to bind OP-1. While it is clear that the extracellular domain of these receptors is capable of binding OP-1, Applicants have not identified which of these residues can be deleted, or substituted, or in any way

altered, and still retain OP-1 binding capabilities. Therefore, Applicants are not enabled for screening assays using proteins other than those comprising the claimed extracellular domains of SEQ ID NO:4, 6 or 8. Applicants have not provided any guidance or working examples of ALK receptors with up to 60% of the protein being altered, or replaced, and which still retains OP-1 binding capabilities, or for any polypeptide which is amplifiable by the claimed peptides of SEQ ID NO:12-15, or which hybridize to nucleotides 256-552 of SEQ ID NO:7. Furthermore, it is not predictable to one of ordinary skill in the art how to make a functional ALK protein other than those of SEQ ID NO:4, 6, or 8.

Finally, Applicants are not enabled for the **scope of cellular responses** recited in claims 2. Applicants have only identified a small number of cellular responses for which to measure the effect of a binding analog (see claim 3).

In summary, the breadth of the claims is excessive with regard to Applicants claiming all methods of identifying binding analogs of proteins which are at least 40% identical to residues 23-132 of SEQ ID NO:8, or any polypeptide chain which is amplified by the primers of SEQ ID NO:12-15, or which hybridizes to residues 256-552 of SEQ ID NO:8. There is also a lack of guidance and working examples of these nucleic acid molecules and proteins as well as which residues are critical for protein function. These factors, along with the lack of predictability to one of ordinary skill in the art as to how to make a functional ALK protein other that those of SEQ ID NO:4, 6 and 8, leads the Examiner to hold that undue experimentation is necessary to practice the invention as claimed.

7. Claim Rejections - 35 USC § 112, first paragraph – written description

A. Claims 1-5 and 8-10 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

These are genus claims. The ALK proteins used in the claimed methods of identifying binding analogs wherein the ALK proteins are **at least 40% identical** to residues 23-132 of SEQ ID NO:8, or any polypeptide chain which is amplified by the **primers** of SEQ ID NO:12-15, or which **hybridize** to residues 256-552 of SEQ ID NO:8 would have one or more amino acid substitutions, deletions, insertions and/or additions to the ALK proteins of SEQ ID NO:4, 6 and 8, or one or more nucleic acid substitutions, deletions, insertions and/or additions to their encoding polynucleotides.

The specification and claims do not indicate what distinguishing attributes are shared by the members of the genus. Thus the scope of the claims includes numerous structural variants, and the genus is highly variant because a significant number of structural differences between genus members is permitted. Although these types of changes are routinely done in the art, the specification and claims do not provide any guidance as to what changes should be made. Structural features that could distinguish compounds in the genus from others in the nucleic acid or protein class are missing from the disclosure. No common structural attributes identify the members of the genus. The general knowledge and level of skill in the art do not supplement the omitted description because specific, not general, guidance is what is needed. Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variant, SEQ ID NO:4, 6, 7, 8, or molecules which hybridize to the polynucleotides encoding these SEQ ID NOs, or which are amplified by the claimed primers of SEQ ID NO:12-15 (which could be at least thousands of molecules) alone are insufficient to describe the genus. One of skill in the art would reasonable conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus, Applicant was not in possession of the claimed genus at the time the invention was made.

In addition, Applicants have not adequately described all of the potential cellular responses recited in claims 2. Applicants have only identified a small number of cellular responses for which to measure the effect of a binding analog (see claim 3).

8. Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-5 and 8-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. Claims 1-5 and 8-10 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: a conclusion step in claims 1, 2 and 8 which states when the method has been completed, for example, "wherein binding of the candidate analog to the protein shows that the candidate analog is analog for the protein."

B. Claims 1, 2 and 8 are confusing since the metes and bounds of "substantially the same binding affinity" are unknown.

C. Claims 1, 2 and 8, parts (i) – (iii) are confusing since ALK-6 is an OP-1 receptor, so it is not understood what is meant by the phrase "or an OP1 binding analog thereof"(i.e. of the receptor).

D. Claims 1, 2 and 8 are vague and indefinite since the claim recites "stringent conditions." It is not known what these conditions are. Nucleic acid molecules which hybridize under conditions of "low" stringency would not necessarily hybridize under conditions of "high" stringency. Furthermore, not all conditions of "high" or "low" stringency, for example, are the same. Therefore, it is required that Applicants amend the claims to recite the exact hybridization conditions without using indefinite phrases such as "*for example*" **without adding new matter**.

E. Claims 2 and 9 are confusing since it is not clear what "cellular response" is being measured in part (c) of the claim. As seen in the above rejections under 35 USC 112, first paragraph, Applicants are only enabled for the assays recited in claim 3.

F. Claims 4, 5 and 10 are confusing since it is not clear what the purpose is of the reporter gene and control element or how this relates to the claimed method, nor is it clear what the purpose is of an additional Type II serine/threonine kinase receptor.

G. Claim 5 recites the limitation "sample" in claims 2 and 3. There is insufficient antecedent basis for this limitation in the claim.

H. Claim 8 is confusing since the phrase "candidate analog comprising part of said sample" is unclear.

9. Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

A. Claims 1-5 and 8-10 are provisionally rejected under the judicially created doctrine of double patenting over one or more claims of copending Application No. 09/267,963. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows: the conflicting application was not available to the Examiner at the time of this Office Action. However, it is known that the claims in both of these Applications are drawn to screening methods.

Furthermore, there is no apparent reason why applicant would be prevented from presenting claims corresponding to those of the instant application in the other copending application. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

10. Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

A. Claims 1-5 and 8-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miyazono et al. (WO 94/11502 - reference AG on the Form PTO-1449 filed 7/22/02) in view of Sampath et al (J. Biol. Chem. 267:20352-20362, 1992 - reference BB on the Form PTO-1449 filed 7/22/02) and further in view

of the Stratagene Catalog (1988, p. 39). The claims recite a method of identifying an OP-1 receptor-binding analog by contacting an ALK-2 protein comprising residues 16-123 of SEQ ID NO:4 (encoded by the DNA of SEQ ID NO:3), an ALK-3 protein comprising residues 24-152 of SEQ ID NO:6 (encoded by SEQ ID NO:5), an ALK-6 protein comprising residues 23-122 of SEQ ID NO:8 (encoded by SEQ ID NO:7), a protein at least 40% identical to the residues of SEQ ID NO:8, those which hybridize to SEQ ID NO:7, or those obtainable with primers of SEQ IDNO:12-15, with a candidate OP-1 receptor-binding analog and detecting the binding.

Miyazono teach ALK-2, 3 and 6 proteins which are believed to be members of the TGF-β superfamily (pages 1-3 of the specification). Miyazono also teach ALK-2, 3 and 6 proteins, which, by definition, have kinase activity, comprising a 100% identical chain to the claimed residues of SEQ ID NO:4, 6 and 8 (Sequence Comparisons A, C, E), the primers of SEQ ID NO:12-15 (Sequence Comparisons G-J), and molecules which hybridize to SEQ ID NO:7 (Sequence Comparison L), as well as the use of screening assays to identify ligands which bind these proteins, including their use in cells (page 7, lines 22-37 of the specification). However, Miyazono do not teach that the ALK proteins bind OP-1.

However, Sampath et al. do teach the protein, OP-1 (Abstract), and that this protein, along with BMPs, are members of the TGF-β superfamily (first paragraph of the Introduction). Sampath et al. also teach assays using OP-1 (Tables I and II and at least Figures 6-9). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to have screened the proteins of Miyazono et al. using OP-1 as a ligand, as taught by Sampath et al. since both Miyazono and Sampath teach proteins which are members of the TGF-β superfamily. Therefore, one would have been motivated to use the OP-1ligand of Sampath to screen the receptors of Miyazono to identify novel binding agents for the ALK receptors of Miyazono. Due to the 100% identity of the proteins (and encoding DNA) of the present invention to those of Miyazono, it would be expected that these proteins would have been obtainable using the primers of SEQ ID NO:12-15 of the present invention.

Neither Miyazono or Sampath teach a kit. However, the Stratagene catalog does teach a motivation to combine reagents of use into a kit (page 39, column 1). It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to combine the materials of Miyazono and Sampath into a kit as taught by Stratagene since the Stratagene catalog teaches a motivation for combining reagents of use in any assay into a kit. It states that "Each kit provides two services: 1) a yariety of different regents have been assembled and premixed specifically for a defined set of experiments. Thus one need not purchase gram quantities of 1 different reagents, each of which is needed in only microgram amounts, when beginning a series of experiments. When one considers all of

the unused chemicals that typically accumulate in weighing rooms, desiccators, and freezers, one quickly realizes that it is actually far more expensive for a small number of users to prepare most buffer solutions from the basic reagents. Stratagene provides only the quantities you will actually need, premixed and tested. In actuality, the kit format saves money and resources for everyone by dramatically reducing waste. 2) The other service provided in a kit is quality control" (page 39, column 1).

B. Claims 1-5 and 8-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Matsuzaki et al. (J. Biol. Chem. 268:12719-12723, 1993 - reference AZ on the Form PTO-1449 filed 7/22/02) in view of Miyazono et al. (WO 94/11502), further in view of Sampath et al (J. Biol. Chem. 267:20352-20362, 1992) and further in view of the Stratagene Catalog (1988).

The claims of the present invention as well as the teachings of Miyazono, Sampath and Stratagene are taught in the above rejection under 35 USC 103. Matsuzaki teach a polypeptide chain 100% identical to SEQ ID NO:4 (Sequence Comparison B). Matsuzaki teach that the protein comprising this chain is a member of the TGF-β superfamily and teach ligand binding assays (Figure 2). However, Matsuzaki do not teach that their protein binds OP-1. However, for the reasons given above for Miyazono and Sampath, the present invention, having a polypeptide chain as taught by Matsuzaki, would have been obvious. Due to the 100% identity of the proteins (and encoding DNA) of the present invention to those of Miyazono, it would be expected that these proteins would have been obtainable using the primers of SEQ ID NO:12-15 of the present invention.

C. Claims 1-5 and 8-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over ten Dijke et al. (Oncogene 8:2879-2887, 1993 - reference BE on the Form PTO-1449 filed 7/22/02) in view of Miyazono et al. (WO 94/11502), further in view of Sampath et al (J. Biol. Chem. 267:20352-20362, 1992) and further in view of the Stratagene Catalog (1988).

The claims of the present invention as well as the teachings of Miyazono, Sampath an the Stratagene Catalog are taught in the above rejection under 35 USC 103. ten Dijke teach a polypeptide chain 100% identical to SEQ ID NO:6 (Sequence Comparison D). ten Dijke teach that the protein comprising this chain is an ALK protein, which is a member of the TGF-β superfamily. However, ten Dijke do not teach that their protein binds OP-1, or screening assays to identify OP-1 receptor-binding analogs. However, for the reasons given above for Miyazono and Sampath, the present invention, having a polypeptide chain as taught by ten Dijke, would have been obvious. Due to the 100% identity of the proteins (and encoding DNA) of the present invention to those of Miyazono, it would be expected that

these proteins would have been obtainable using the primers of SEQ ID NO:12-15 of the present invention.

D. Claims 1-5 and 8-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over ten Dijke et al. (Science 264:101-104, 1994 - reference BF on the Form PTO-1449 filed 7/22/02) in view of Miyazono et al. (WO 94/11502), further in view of Sampath et al (J. Biol. Chem. 267:20352-20362, 1992) and further in view of the Stratagene Catalog (1988).

The claims of the present invention as well as the teachings of Miyazono, Sampath and the Stratagene Catalog are taught in the above rejection under 35 USC 103. ten Dijke teach a polypeptide chain 100% identical to SEQ ID NO:8 (Sequence Comparison F) and which would hybridize to SEQ ID NO:7 (Sequence Comparison K). ten Dijke teach that the protein comprising this chain is an ALK protein, which is a member of the TGF-β superfamily. However, ten Dijke do not teach that their protein binds OP-1, or screening assays to identify OP-1 receptor-binding analogs. However, for the reasons given above for Miyazono and Sampath, the present invention, having a polypeptide chain as taught by ten Dijke, would have been obvious. Due to the 100% identity of the proteins (and encoding DNA) of the present invention to those of Miyazono, it would be expected that these proteins would have been obtainable using the primers of SEQ ID NO:12-15 of the present invention.

11. Conclusion

A. No claim is allowable.

Advisory information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Landsman whose telephone number is (703) 306-3407. The examiner can normally be reached on Monday - Friday from 8:00 AM to 5:00 PM (Eastern time) and alternate Fridays from 8:00 AM to 5:00 PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623.

Official papers filed by fax should be directed to (703) 308-4242. Fax draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Robert Landsman, Ph.D.
Patent Examiner
Group 1600
May 08, 2003

ROBERT LANDSMAN
PATENT EXAMINER